UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

FOSAMAX PRODUCTS LIABILITY LITIGATION

MASTER FILE
No. 1:06-md-01789-JFK-JCF

This document relates to:
Linda Secrest v. Merck & Co., Inc.

Case No.: 1:06-cv-06292-JFK

MEMORANDUM OF AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION IN LIMINE

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COMES NOW LINDA SECREST, Plaintiff herein, and presents this memorandum of authorities in support of her motion in limine, showing this Court that it should exclude the following evidence from the trial in this case.

I. DEFENDANT SHOULD NOT BE PERMITTED TO OFFER ANY EVIDENCE CONCERNING MRS. SECREST'S LAWSUIT OR THE DISCIPLINARY PROCEEDINGS AGAINST HER FORMER DENTIST, DR. ALEXANDER.

This Court should exclude reference to and any evidence concerning Linda Secrest's prior malpractice litigation against Dr. Stephen Alexander relating to "ill-fitting crowns and bridges". While the treatment records of Dr. Alexander are admissible for Linda Secrest's medical and dental history, the fact that she filed a malpractice claim for treatment from 1999 to 2001 has no probative value and the potential prejudicial impact would thus far outweigh the probative value. None of Merck's experts will testify that Dr. Alexander violated the standard of care he owed to Linda Secrest. Evidence of Mrs. Secrest's prior litigation against her dentist Dr. Alexander and the disciplinary proceedings related thereto are collateral matters that should not be relitigated in this case for the bisphosphonate-related osteonecrosis of the jaw which occurred three years after Mrs. Secrest last received any treatment for her teeth from Dr. Alexander.

A. The Federal Rules of Evidence and Florida Law Demonstrate That This Court Should Exclude Evidence of the Prior Litigation.

1. Neither Defendant's Experts Nor Plaintiff's Experts Opine That Dr. Alexander Violated the Standard of Care.

Dentist Dr. Steven Alexander had Linda Secrest as a patient beginning in 1999 and ending a year and a half later. (Linda Secrest depo., pp. 11-12, Exh. 1 hereto.) Describing the dental work performed by Dr. Alexander, Mrs. Secrest testified: "He did several crowns and bridges, took several impressions, and nothing ever stayed in my mouth, nothing worked, no

temporary stayed; nothing worked." (Secrest depo., p. 12.) He did not put any implants into Mrs. Secrest's jaw. His work was just on her teeth. (Secrest depo., p. 13.) Mrs. Secrest filed suit against Dr. Alexander in 2002 or 2003. (Secrest depo., p. 11.) When asked why she sued him, Mrs. Secrest testified: "For ill-fitting crowns and bridges." (Secrest depo., p. 11.)

"To prevail in a medical malpractice case a plaintiff must establish the following: the standard of care owed by the defendant, the defendant's breach of the standard of care, and that said breach proximately caused the damages claimed." *Gooding v. University Hosp. Bldg., Inc.*, 445 So.2d 1015, 1018 (Fla. 1984). No expert witness for Defendant has opined that Dr. Alexander violated the standard of care owed to Linda Secrest. While everyone has access to Dr. Alexander's dental records, the litigation pursued by Linda Secrest against Dr. Alexander is not relevant to any expert opinions in this case.

In response to express questions by Mrs. Secrest's counsel about the issue, Dr. Betts ultimately conceded that he was not going to testify that Dr. Alexander violated the standard of care he owed to Linda Secrest:

Q: . . . My question is do you believe personally, do you believe that Dr. Alexander violated the standard of care?

A: I think that --

MR. HECHT: Objection.

THE WITNESS: -- his -- I will answer as best I can. I think his work was contributory to the problems that she developed.

Q: My question is did he violate the standard of care?

MR. HECHT: Objection, form.

THE WITNESS: That's difficult for me to assess. I think it's important for you to

understand that I was not asked in this case to make a determination as to whether Dr. Alexander did or did not violate the standard of care. I was asked to review the records to see whether or not bisphosphonates were a factor in Miss Secrest's problems that she developed, and so I had not really thought about that as far as a standard of care.

Q: But you cite the Florida Department of Health findings[1]. Did you just -- why did you even cite the Florida Department of Health findings if that's not part of your analysis in this case, the standard of care issue?

A: Well, I think it's evidence that his work was -- was assessed by an outside, supposedly noninvolved party, and their feeling was that he had violated those issues.

Q: Right. But what is it relevant to Miss Secrest? Is it relevant in any particular way to your opinions, that is Dr. Betts' opinions relating to Miss Secrest?

A: Well, my feeling --

MR. HECHT: Object to the form.

THE WITNESS: -- my feeling is that Miss -- that Dr. Alexander's treatments in two different ways have contributed to her subsequent problems.

Q: Do you have any opinion of your own as to whether Dr. Alexander violated the standard of care?

MR. HECHT: Object to the form, asked and answered.

THE WITNESS: I personally think that he had issues that were contributory to her infections. And I'm trying not to address the issue of standard of care because I wasn't asked to do that.

Q: My question is do you have an opinion as to whether he violated the standard of care?

MR. HECHT: Object to the form, asked and answered.

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[1] As presented further below, there were no formal findings between the Florida Department of Health and Dr. Alexander. Rather, there was a an "informal disposition" pursuant to Fla. Stat. § 120.57(4) which constituted an expressly negotiated compromise and settlement between Dr. Alexander and the allegations that Dr. Alexander's placement of crowns on her teeth (not jaw) were deficient.

THE WITNESS: My opinion is that other agencies have already done that and, therefore, I don't need to, and they found that he did.

Q: Right. My question is do you believe -- I understand that you cited the other agency, but that's privileged under Florida law. My question is do you have a personal opinion and do you intend to testify that Dr. Alexander violated the standard of care?

A: I'm not going to testify --

MR. HECHT: Hold on, Dr. Betts. Object to the form, and I object to the comments by counsel about admissibility. It's just not appropriate for deposition.

THE WITNESS: I am going to testify -- what I am going to testify is that I think the work that he did was contributory in her problems.

Q: All right.

A: I am not going to testify to the standard of care for him.

(Dr. Norman Betts depo, pp. 70-73, Exh. 2 hereto.)

Similarly, Defendant's only other case-specific expert, rheumatologist Dr. Barry Gruber who is being offered on both efficacy and causation grounds, testified that he has no opinion relating to Dr. Alexander's alleged violation of the standard of care:

Q: Do you believe yourself qualified to testify relating to the standard of care for oral surgeons?

A: No, I don't believe so. Not being an oral surgeon I couldn't say that I would be an expert in talking about the standard of care for oral surgery.

(Dr. Barry Gruber depo., p. 41, Exh. 3 hereto.) Further:

Q: Do you have an opinion that any of Linda Secrest's providers violated any standard of care with respect to their treatment of Linda Secrest?

MR. HECHT: Objection to the form of the question.

A: Again, Linda Secrest had a multitude of providers that took care of her

> oral cavity, who took care of her general health, and took care of her rheumatic and gynecologic issues. As we spoke about before, I don't know that I'm an expert to speak to all of the dental providers.
>
> Q: Okay.
>
> A: So I can't answer that question when it relates to her dental providers as to whether they provided the standard of care.

(Gruber depo., pp. 44-45)

Similarly, Mrs. Secrest's treating oral surgeon Dr. Robert Marx testified that by the time he treated Linda Secrest, she was not dealing with any residual ill effects from the dental treatment provided by Dr. Alexander. (Dr. Robert Marx 2011 depo., pp. 113-114, Exh. 4 hereto.)

2. Florida Law and the Federal Rules of Evidence Bar Admission of Mrs. Secrest's Prior Litigation Against and Settlement with The Third Party.

Mrs. Secrest's lawsuit suit against her former dentist, Dr. Alexander, is not relevant to the matters at issue in this case. However, even if the Court finds that this prior suit is relevant, the Court should exclude this testimony pursuant to FRE 403, as such testimony is unfairly prejudicial, confuses the issues, and will only serve to mislead the jury. Furthermore, any testimony concerning Dr. Alexander's settlement of this lawsuit is also clearly inadmissible under Florida law. The Court should prohibit Merck from presenting any testimony concerning the lawsuit filed by Mrs. Secrest against Dr. Alexander or the subsequent settlement thereof.

a. Evidence of the Prior Litigation is Inadmissible.

Mrs. Secrest's lawsuit against her former dentist, Dr. Alexander, is not relevant to this case. Quite simply, the fact that Mrs. Secrest filed suit against Dr. Alexander does not make it more or less probable that Fosamax caused Mrs. Secrest's osteonecrosis of the jaw. This Court

has consistently prohibited testimony concerning the Vioxx litigation where Merck was a defendant on relevancy grounds. (Boles I MIL Hrg. Tr., p. 479, Exh. 5 hereto). Further, this Court has stridently endeavored to ensure that Merck's other Fosamax litigation cases are not referenced in front of the jury, including issuing a show-cause order to co-counsel in the Boles II trial relating to same. (Boles II Trial TR, pp. 230, 984-86, Exh. 6 hereto; 07/07/10 Order to Show Cause, p. 2, Exh. 7 hereto.)

Testimony concerning Mrs. Secrest's suit against Dr. Alexander should be treated similarly and Florida law and the Federal Rules of Evidence show that any such evidence or reference should be excluded, even if the alleged injury in the instant lawsuit is the same as in the prior lawsuit.

In the Florida Statutes, Chapter 768 pertaining to the substantive law of negligence in Florida, Section 768.041(3) requires the Court to consider issues relating to set-off post-trial: "The fact of such a release or covenant not to sue, or that any defendant has been dismissed by order of the court shall not be made known to the jury." Florida courts interpreting this statutory provision hold that evidence of prior litigation arising from the same injury should be excluded from the jury's consideration.

For instance, in the case of *Ed Ricke and Sons, Inc. v. Green*, 468 So.2d 908 (Fla. 1985), the Florida Supreme Court considered the issue of the inadmissibility of prior lawsuits. In that case, a child was scalded over most of his body after he fell into a deep puddle of boiling water. *Id.* at 909. Dade County was responsible for maintaining the water heater which had previously been installed by Ed Ricke and Sons, Inc. *Id.* Green sued and settled with Dade County. *Id.*; *Green v. Ed Ricke and Sons, Inc.*, 438 So.2d 25, 26 (Fla. 3rd DCA 1983). Thereafter, Green filed

suit against Ed Ricke and Sons for the same injuries. *Green*, 438 So.2d at 26. For the Ricke trial, the court entered an order in limine prohibiting evidence of the prior lawsuit and/or settlement arising out of the subject accident. *Id.*

During the trial in *Ricke*, defense counsel employed the empty chair defense, made reference to a deposition in the "initial suit", and made reference to plaintiff's counsel "blaming everybody". *Id.* at 26-27; *Ed Ricke and Sons*, 468 So.2d at 909. The jury returned a defense verdict. *Ed Ricke and Sons*, 468 So.2d at 909. On appeal, both the Third District Court of Appeal and the Florida Supreme Court concluded that the plaintiff was entitled to a new trial because of the references to the prior litigation. *Green*, 438 So.2d at 27-28; *Ed Ricke and Sons*, 468 So.2d at 909-10.

In so ruling, the Third District Court of Appeal determined that the references and innuendo to prior litigation "violated not only the pretrial order, but also the spirit of Section 768.041(3), Florida Statutes (1981), which provides: 'The fact of . . . a release or covenant not to sue, or that any defendant has been dismissed by order of the court shall not be made known to the jury.'" *Green*, 438 So.2d at 27; *see also Webb v. Priest*, 413 So.2d 43 (Fla. 3rd DCA 1982) (holding that defendant's reference to prior defendants constituted basis for new trial, even though neither the fact of the settlement nor the terms of the agreement were mentioned). Citing *Webb*, the *Green* court observed: "By less flagrant but equally as effective means, the same was accomplished here. Dade County was not a party to the lawsuit because it had been released, and it was improper to make its absence a feature of the trial." *Green*, 438 So.2d at 27.

The Florida Supreme Court agreed with the intermediate appellate court's analysis: "The closing argument was not just a traditional empty chair argument. Defense counsel did more

than simply argue that Dade County was responsible for the accident. Rather, defense counsel emphasized that there had been a prior suit against that empty chair." *Ed Ricke and Sons*, 468 So.2d at 909; *see also Susan Fixel, Inc. v. Rosenthal & Rosenthal, Inc.*, 921 So.2d 43, 48 (Fla. 3rd DCA 2006) (finding plaintiff's prior litigation history and existence of prior defendants was not admissible).

While Defendant may argue that Mrs. Secrest's injuries were caused by Dr. Alexander, that fact does not require the introduction of litigation evidence. Rather, the jury can consider that fact based upon the medical records themselves. *See, e.g., Colvin v. Williams*, 564 So.2d 1249, 1251 (Fla. 4th DCA 1990) ("[w]hile the questions of prior *injuries* was relevant, this inquiry could have been conducted without reference to the use of permanent impairment ratings in connection with litigation") (emphasis in orig.).

Further diminishing the relevance of testimony concerning this prior suit is the fact that the suit alleged negligence on the part of Dr. Alexander for dental work that he performed from 1999 to 2001. These allegations have no bearing on the instant case, as Mrs. Secrest did not have ONJ or osteomyelitis, even by Merck's own expert's approximation, until at least 2004. (Betts Dep., p. 33-34, 93). Instead, such evidence could only be offered in an attempt to convince the jury that Mrs. Secrest has a propensity for litigation.

This evidence is also inadmissible pursuant to Federal Rules of Evidence 403 and 404.

The Second Circuit has expressed significant concern of allowing evidence of prior lawsuits and outcomes to be considered by a subsequent jury, even where the prior lawsuits are related to the one on trial, as the risk of unfair prejudice outweighs the probative value under Rule 403. *United States Football League v. National Football League*, 842 F.2d 1335, 1372-73

(2nd Cir. 1988); *see also Eng v. Scully*, 146 F.R.D. 74, 79 (S.D.N.Y. 1993) (Lowe, J.) (excluding evidence of plaintiff's prior litigations) *and Greenfield v. City of New York*, 2000 WL 124992, *11 (S.D.N.Y. 2000) (Peck, Mag.J.) (same). *Cf. Wilson v. Zielke*, 2009 WL 1285867, *5 (E.D. Pa. 2009) ("[w]hile evidence of the prior injury sustained during the WaWa incident is relevant as to causation and damages, evidence of the prior lawsuit related thereto is irrelevant and prejudicial").

Further, Second Circuit authority clearly holds that Rule 404(b) (evidence of other crimes, wrongs, or acts) mandates exclusion of prior litigation for purpose of proving litigiousness. "Litigiousness is the sort of character trait with which Rule 404(b) is concerned." *Outley v. City of New York*, 837 F.2d 587, 592 and 592-95 (2nd Cir. 1988) (reversing judgment for defense where trial court erroneously admitted evidence showing that plaintiff had filed prior suits and defendants argued about those prior suits); *see also Raysor v. Port Authority of New York and New Jersey*, 768 F.2d 34, 40 (2nd Cir. 1985) (precluding evidence of a *pro se* litigants extensive litigation on other matters as whatever slight probative value existed was outweighed by the substantial danger of jury bias against a chronic litigant).

Even if the Court finds that testimony concerning Mrs. Secrest's suit against Dr. Alexander is relevant, such testimony should be excluded pursuant to FRE 403. Testimony concerning Mrs. Secrest's suit against Dr. Alexander would create unfair prejudice, confuse the issues, and mislead the jury. If testimony was permitted on this issue, the jury would be left to infer that Mrs. Secrest has already recovered for her injuries, even though the injuries claimed here are different and distinct from those at issue in this prior suit. As such, the jury would be misled and the issues actually involved in this case would be confused. Furthermore, Mrs.

Secrest would be unfairly prejudiced by the possibility that jurors would feel that she was seeking a second bite at the apple by now filing suit against Merck.

b. Federal Rule 408 Bars Evidence of Mrs. Secrest's Settlement with a Third Party.

The Court should also prohibit Merck from offering any testimony or evidence showing that Dr. Alexander settled the lawsuit filed by Mrs. Secrest. Mrs. Secrest anticipates Merck will attempt to introduce evidence of the settlement between Dr. Alexander and Mrs. Secrest during the trial of this case. However, it is improper for the jury to hear evidence of collateral source benefits because it may "lead the jury to believe that [the plaintiff] was trying to obtain a double or triple payment for one injury." *Cook v. Eney*, 277 So.2d 848, 850 (Fla. 3d DCA 1973).

Additionally, Mrs. Secrest anticipates that Merck will argue Dr. Alexander is a joint tortfeasor and Merck is entitled to a setoff for Dr. Alexander's contribution to her injury. Florida law is clear that any setoffs are to be decided by the Court after a jury verdict is reached. See Florida Statutes § 768.76(1). Even if this amount were subject to setoff (which it is not), "there must first be an award by the jury of damages for which collateral sources are available before any collateral source setoff may be made." *Odom v. Carney*, 625 So.2d 850, 851 (Fla. 4th DCA 1993).

Likewise, Federal Rule of Evidence 408 excludes evidence of complete compromises and settlements with third parties and prior defendants. *In re Homestore.com, Inc.*, 2011 WL 291176, *1 (C.D. Cal. 01/25/11); *see also Young v. Verson Allstate Press Co.*, 539 F.Supp. 193, 195-96 (E.D. Pa. 1982). "It is well established that settlement that statements made for the purposes of settlement negotiations are inadmissible and Rule 408 of the Federal Rules of

Evidence extends that exclusion to completed compromises when offered against the compromiser." *Playboy Enterprises, Inc. v. Chuckleberry Pub., Inc.*, 486 F.Supp. 414, 423 n.10 (S.D.N.Y. 1980) (Sofaer, J.); *see also* Fed. R. Evid. 408, advisory committee note.

The First Circuit Court of Appeals explained the policy underlying Rule 408 and why it precludes admission of evidence of settlements with third parties in *McInnis v. A.M.F., Inc.*, 765 F.2d 240 (1st Cir. 1985). In *McInnis*, the injured plaintiff had settled with a third party who was not a defendant in the then-pending litigation. *Id.* at 246. At trial, the defendant successfully persuaded the trial court to admit into evidence the fact of the settlement with the third party as well as the release on the theory that the third party had caused the injury, rather than the current defendants. *Id.* At trial, the defendants cross-examined the plaintiff about the release as well as the $60,000.00 she received pursuant to that settlement agreement. *Id.* at 248. The jury returned a verdict for the defendants and the plaintiff appealed. *Id.* at 241.

On appeal, the First Circuit reversed and ordered a new trial, ruling the trial court violated Federal Rule of Evidence 408 by admitting the release. *Id.* at 246-47. In analyzing Rule 408, the *McInnis* court addressed why the very purpose of rule mandated exclusion: first, the public policy goal of promoting compromise and settlement of claims; second, the limited relevance of settlement evidence since "settlement may well reflect a desire for peaceful dispute resolution, rather than the litigants' perceptions of the strengths of their relative positions. *See* Fed.Rule of Evid. 408, advisory committee note." *Id.* at 247.

On the issue of whether Rule 408 applies to settlements with third parties, the First Circuit again analyzed the advisory committee note and determined that the purposes of Rule 408 apply with equal force in such situations:

> In analyzing the impact of Rule 408 on the admissibility of the Poirier release, we shall initially allay any doubts that the Rule applies to cases which are posturally like the one now before us. The settlement agreement at issue here was entered into between a litigant and a third party, rather than between the two litigants themselves. The Advisory Committee Note clearly acknowledges the policies underlying the exclusionary rule are equally applicable to such a situation. The note states that: "While the rule is ordinarily phrased in terms of offers of compromise, it is apparent that a similar attitude must be taken with respect to completed compromises when offered against a party thereto. *The latter situation will not, of course, ordinarily occur except when a party to the present litigation has compromised with a third person.*" Fed.Rule of Evid. 408, advisory committee note (emphasis added [by *McInnis* court]).

Id.

The *McInnis* court then cited the Second Circuit's decision in *Sun Oil v. Govostes*, 474 F.2d 1048, 1049 (2nd Cir. 1973) which excluded the admission of a defendant's settlement agreement with a third party. In *McInnis*, the trial court admitted the plaintiff's settlement agreement with a third party. 765 F.2d at 247. The First Circuit reasoned that the policy underlying Rule 408 applies with equal strength regardless of whether evidence of the third party settlement is offered against a plaintiff or defendant in the litigation *sub judice*. *Id.* "If the policies underlying Rule 408 mandate that settlements may not be admitted against a defendant who has recognized and settled a third party's claim against him, it is axiomatic that those policies likewise prohibit the admission of settlement evidence against a plaintiff who has accepted from a third party against whom he has a claim." *Id.*

The *McInnis* defendants attempted to argue that the settlement release was offered for "other purposes" (i.e., to attack the plaintiff's credibility) and thus allowable under Rule 408. The First Circuit rejected that argument as pretextual: "The release could logically impeach McInnis' credibility only by tending to show that she brought suit against the defendants

knowing all the while and it was Mrs. Poirier, and not the defendants, who caused the injury. *Such 'impeachment' evidence is simply camouflaged causation evidence.*" *Id.* at 248 (emphasis added).

Because the settlement release with the third party was offered for the purpose of alternate causation defense, the First Circuit determined that Rule 408 applied:

> [W]e have no difficulty in ruling that the evidence of causation or non-causation is fully subsumed under Rule 408's meaning of validity or invalidity of a claim. Causation in fact is an integral component of a tort claim; without causation there can be no liability. In the instant case, it is obvious that the defendants wanted the jury to infer that Mrs. Poirier would not have paid the significant sum of $60,000 to the plaintiff unless it was she, *and not the defendants*, who had caused the plaintiff's injury. Whether case in terms of "causation", "responsibility", or the "validity of the claim", the defendants wanted the jury to conclude from the fact of the settlement that the defendants could not be held liable for the amputation of the plaintiff's leg. This clearly flouts the most basic policies underlying Rule 408.

Id. at 248-49 (emphasis in orig.).

In analyzing the prejudice to the plaintiff, the *McInnis* court cited the pre-Federal Rules of Evidence Second Circuit case of *Paster v. Pennsylvania R.R.*, 43 F.2d 908, 911 (2nd Cir. 1930) (trial court's failure to exclude evidence of a settlement agreement was generally considered sufficiently prejudicial to warrant a new trial). 765 F.2d at 251. Further, the *McInnis* court observed that the prejudice of such admission was so profound that it was highly doubtful that any limiting instruction, "no matter how clear and comprehensive, could eradicate the prejudice engendered by the admission of the release in this case." *Id.* at 252; *see also Highland Capital Management, L.P. v. Schneider*, 551 F. Supp.2d 173, 199 (S.D.N.Y. 2008) (Leisure, J.) (excluding, pursuant to Rules 403 and 408, evidence of plaintiff's settlement agreement with third party).

For the foregoing reasons, Merck should not be permitted to offer any evidence or testimony concerning the fact that Mrs. Secrest filed suit against Dr. Alexander or that the suit was subsequently settled.

B. Merck Should Not Be Permitted to Offer Testimony or Evidence Concerning Dr. Alexander's Settlement with the Florida Department of Health.

Merck should not be permitted to offer any testimony or evidence related to the disciplinary action taken by the Florida Department of Health against Dr. Alexander. The disciplinary documents are not relevant to the facts at issue in this case. Further, the information contained within the disciplinary documents is hearsay, and doesn't meet any recognized exception to the hearsay rule. Finally, even if this information is found to be otherwise admissible, it should be excluded because it is unduly prejudicial and has extremely limited probative value.

Mrs. Secrest anticipates Merck will attempt to elicit testimony and admit record evidence concerning a disciplinary action taken by the Florida Department of Health (hereinafter "Department") against Dr. Alexander. Dr. Alexander signed a stipulation on October 10, 2005 wherein he admitted "the factual allegations contained in the complaint for the purposes of settlement in these administrative proceedings only." (10/10/05 Stipulation, 120LLSECREST-146FDH-00009-00018, at Exh. 8 hereto). The Department's complaint, filed on November 30, 2005, alleged Dr. Alexander failed to meet "prevailing peer performance" standards related to dental work performed on Mrs. Secrest and for poor record-keeping (Administrative Complaint, 120LLSECREST-146FDH-00019-00028, at Exh. 8 hereto).[2] A review of the Stipulation and the

[2]Although, the initials "L.S." appear several times in the complaint as the patient at issue, Mrs. Secrest is never named in the complaint or in the stipulated agreement between Dr. Alexander and the

attached administrative complaint reveals that the complained-of work relates solely to Dr. Alexander's placement of crowns on teeth; he did no surgery of any type of Mrs. Secrest's jaw. Dr. Alexander and the Department negotiated the stipulation and thereby Dr. Alexander waived his right to a finding of probable cause. (Final Order, 120LLSECREST-146FDH-00007-00008, at Exh. 8 hereto, Waiver of Probable Cause, 120LLSECREST-146FDH-00029-00031, at Exh. 8 hereto.)

1. The Disciplinary Documents Are Inadmissible Hearsay.

The stipulated agreement, complaint, and all other documentation created as a part of the disciplinary proceedings against Dr. Alexander are inadmissible hearsay. Mrs. Secrest anticipates that Merck will attempt to use the disciplinary documents from the Department to prove the truth of the matter asserted therein; namely that Dr. Alexander performed substandard dental work on Mrs. Secrest. As these documents do not meet any of the recognized hearsay exceptions, they must be excluded.

The disciplinary documents are not public records pursuant to FRE 803(8). FRE 803(8) excepts the following documents from the hearsay rule:

> Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report, excluding, however, in criminal cases matters observed by police officers and other law enforcement personnel, or (C) in civil actions and proceedings and against the Government in criminal cases, factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.

The stipulated agreement and complaint do not fit within the definition of FRE 803(8)(A)

Department.

or (B). These documents also do not meet the definition of 803 (8)(C). However, at least some discussion of this subsection is warranted.

FRE 803(8)(C) applies to "factual findings resulting from an investigation made pursuant to authority granted by law." "The term 'factual findings' has been construed to include opinions or conclusions based upon investigations." *Lewis v. Velez*, 149 F.R.D. 474, 487 (S.D.N.Y. 1993) (Francis, Mag.J.). After an exhaustive search, Mrs. Secrest could find no federal case law ruling administrative complaints or negotiated settlement documents between and administrative agency and a private citizen constitute "factual findings". Instead, accusatory documents such as a disciplinary notice of infraction do not fall within the definition of FRE 803(8)(C). *Id.* at 485

The stipulation itself is nothing more than an agreement entered into between Dr. Alexander and the Department. No findings of fact are made anywhere within the document. Therefore, the stipulation clearly doesn't fall within the ambit of 803(8)(C).

The Administrative Complaint also does not include factual findings. The stipulation specifically states "[r]espondent (Dr. Alexander) admits the factual *allegations* contained in the Complaint for the purposes of settlement in these administrative proceedings only." (Stipulation, p. 2) (emphasis added). The stipulation itself is clearly worded to state that the facts contained in the complaint are allegations, rather than findings. To the contrary, Dr. Alexander simply admitted to the allegations made by the Department, thereby making factual findings unnecessary. To this point, the statute governing disciplinary proceedings states:

> When its investigation is complete and legally sufficient, the department shall prepare and submit to the probable cause panel of the appropriate regulatory board the investigative report of the department. The report shall contain the *investigative findings* and the recommendations of the department concerning the existence

of probable cause.

Florida Statutes § 456.073(2). (emphasis added).

No investigative report was completed by the department in this case, thus the department made no factual findings contemplated by FRE 803(8)(C). As no probable cause hearing was ever held, no factual findings were made by the probable cause panel either.

Even if the Court finds that the stipulation and/or Administrative complaint include factual findings within the scope of FRE 803(8)(C), the inquiry does not stop there. FRE 803(8)(C) provides that factual findings from an investigation are admissible, "unless the sources of information or other circumstances indicate a lack of trustworthiness." The advisory committee's note to the rule recommends the consideration of four factors in assessing trustworthiness:

> (1) the timeliness of the investigation; (2) the special skill or experience of the reporter; (3) whether a hearing was held in conjunction with the investigation, the level at which the hearing was conducted, and the procedures invoked; and (4) any motive on the part of the informant that could interfere with accuracy.

See Fed. R. Evid. 803 advisory committee's note.

The Second Circuit has adopted these factors for the review of trustworthiness of documents offered under FRE 803(8)(C). *See Lewis*, 149 F.R.D. at 487. Application of the trustworthiness factors to the stipulation and the administrative complaint lead to the conclusion that these documents are not trustworthy and thus exclusion is warranted under FRE 803(8)©.

First, it is unclear whether the allegations included in the administrative complaint were gathered in a timely fashion. "The timeliness factor evolved out of concern over staleness or tampering with evidence." *Gentile v. County of Suffolk*, 129 F.R.D. 435, 450 (E.D.N.Y. 1990),

aff'd, 926 F.2d 142 (2d Cir. 1991). The Department's records do not include the actual complaint filed by Mrs. Secrest, thus it is unclear whether the Department's allegations against Dr. Alexander were prepared in a timely fashion. However, the dental work at issue in the first count of the complaint occurred between 1999 and 2001, thus raising a serious timeliness concern, given that the Department did not take any disciplinary action against Dr. Alexander until late 2005.

Second, there is no evidence that the allegations included within the administrative complaint were the work product of anyone with special skill or experience. The administrative complaint was drafted by an attorney for the Department, presumably for the purpose of making allegations that met the legal requirements for disciplinary action. However, it is clear that many of the allegations contained within the complaint could only have been obtained through discussions with Dr. Alexander or Mrs. Secrest. As such, much of the information contained within the complaint is hearsay. Hearsay portions of the complaint must be "adequately evaluated and filtered by a reporting body that in effect qualified as an expert under Rules 702 and 703 of the Federal Rules of Evidence." *Id* at 453. There is no evidence in this case that a medical expert prepared or evaluated the information contained within the complaint prepared by the Department's attorney. In fact, the expert body responsible for evaluating such evidence was the probable cause board and no probable cause hearing was conducted during these disciplinary proceedings.

As discussed previously, no hearing was conducted related to the discipline of Dr. Alexander. Thus, no fact-finding body ever evaluated the allegations made within the complaint filed by the Department, to ensure that they were in fact supported by the evidence. Even more

telling is the fact that the complaint was drafted and filed more than a more after the stipulation between the Department and Dr. Alexander was reached. Therefore, the Department could include any factual allegations it desired without any procedural recourse being available to Dr. Alexander to dispute the accuracy of such allegations. Such "findings cannot be deemed trustworthy where they emerge from proceedings . . . that are notably lacking in procedural safeguards." *Zenith Radio Corp. v. Matsushita Electrical Industrial Co., Ltd.,* 505 F. Supp. 1125, 1148 (E.D. Penn. 1980), *reversed on other grds.*, 723 F.2d 223 (3rd Cir. 1983)..

Finally, there is a clear motivation by each party that taints the trustworthiness of the stipulation and the administrative complaint. Both parties drafted the stipulation and the corresponding administrative complaint on the basis of mutual consideration. Dr. Alexander agreed to stipulate to undisclosed and undetermined factual allegations and legal conclusions in exchange for a somewhat lenient disposition that included a $6,000 fine, investigative costs, a refund to the patient of out-of-pocket expenses, 39 hours of continuing education courses, and a Laws and Rules Examination. (See Stipulation, pp. 3-5). This disposition is somewhat lenient because Dr. Alexander could have faced penalties as severe as a $20,000 fine, probation, limitations on his ability to practice dentistry, or permanent revocation of his dentistry license as a result of these allegations. See 64 FL ADC 64B5-13.005 (Exh. 9 hereto).

Additionally, the Department had a motivation to include legal sufficient allegations in the administrative complaint to support the previously executed stipulation. This motivation was further left unchecked by Dr. Alexander's inability to dispute the allegations include in the administrative complaint. He signed the stipulation admitting to undetermined factual allegations and legal conclusions more than a month prior to the drafting of the administrative

complaint. As such, there is a clear motivation for Dr. Alexander to admit to undetermined factual allegations in order to save his license and for the Department to allege legally sufficient facts to support its previously executed agreement with Dr. Alexander.

In conclusion, the stipulation and the administrative complaint are not sufficiently trustworthy to warrant admission under FRE 803 (8)(C). It is unclear whether the disciplinary action pursued against Dr. Alexander was done in a timely fashion. However, it is undisputable that the conduct that was the subject of the administrative complaint and stipulation occurred several years before the disciplinary action was brought, thus raising serious staleness concerns. There is also no evidence that the administrative complaint included factual allegations collected by one with special skill or experience. Furthermore, there was no hearing conducted where probable cause was found and no other due process safeguards were attendant to the administrative complaint or stipulation. Finally, there was a clear motivation by the Department and Dr. Alexander that raises trustworthiness questions related to the administrative complaint and stipulation. Therefore, the administrative complaint and stipulation do not meet any of the trustworthiness factors, thus exclusion under FRE 803(8)(C) is warranted.

2. The Disciplinary Documents Are Not Relevant to this Case.

The stipulated agreement, complaint, and any other documentation or testimony related to the Department's disciplinary action against Dr. Alexander are not relevant to this case and should therefore be excluded by this Court. The treatment at issue in the disciplinary proceedings involved purely dental (i.e., crowns) procedures performed by Dr. Alexander between 1999 and 2001. (Administrative Complaint, p. 2). This spans a time period that is 3 to 5 years before the osteonecrosis or osteomyelitis diagnosis dates postulated by Merck's expert.

(Betts depo., pp. 33-34, 93). As such, disciplinary action taken by the Department as a result of procedures performed several years prior to the injury at issue in this case is simply not relevant. Merck's experts have refused to independently opine that Dr. Alexander violated the standard of care and that any such violation of the standard of care caused the osteonecrosis of the jaw and osteomyelitis complained-of by Linda Secrest in the current case.

3. Even If the Court Finds That the Disciplinary Documents Are Relevant, The Prejudicial Value So Outweighs the Probative Value that Rule 403 Requires Their Exclusion.

Exclusion of the administrative complaint and stipulation is required by FRE 403. The factual allegations contained in the administrative complaint are available to Merck's expert witnesses thus making testimony or record evidence concerning the disciplinary proceedings against Dr. Alexander a cumulative presentation of evidence and a waste of the jury's time. Moreover, there is a clear danger of unfair prejudice to Mrs. Secrest as the jury is likely to give the factual allegations contained within the administrative complaint and the stipulated sanctions undue weight.

The factual allegations contained within the administrative complaint were presumably a product of Dr. Alexander's treatment records. Merck's expert witnesses are in possession of Dr. Alexander's treatment records. Merck's experts are free to provide their opinion that Dr. Alexander provided substandard care to Mrs. Secrest and in fact have all of the treatment records reviewed by the Department in order to do so. As such, admission of the administrative complaint and stipulation would be cumulative evidence with little independent probative value. *See Tulloss v. Near N. Montessori Sch., Inc.*, 776 F.2d 150, 152-55 (7th Cir. 1985) (holding district court appropriately to refuse to admit EEOC findings of reasonable cause where the

evidence available to the EEOC was also available to the parties in litigation); *Young v. James Green Management Inc.,* 327 F.3d 616, 623-25 (7th Cir. 2003) (finding no probative value in EEOC reasonable cause findings where information used as basis of those findings was otherwise available to the jury during trial).

The jury is also likely to be confused about the import of the administrative documents and is likely to give undue weight to the stipulation and the factual allegations and legal conclusions within the administrative complaint. Courts have consistently excluded administrative findings because of the undue weight likely to be given them by the jury. *See City of New York v. Pullman, Inc.,* 662 F.2d 910, 915 (2nd Cir. 1981) (holding administrative report of Urban Mass Transit Administration was properly excluded under FRE 403 "because the likelihood that it would confuse the jury and protract the proceedings outweighed its probative value."); *Martin v. Cavalier Hotel*, 48 F.3d 1343, 1358 (4th Cir. 1995) (finding trial court properly excluded report of state employment commission that Title VII plaintiff left her job voluntarily "because jury would have placed undue weight on such evidence."); *Williams v. Nashville Network*, 132 F.3d 1123, 1128-30 (6th Cir. 1997) (holding trial court properly excluded EEOC probable cause letter because the jury might have attached undue weight to the findings within the letter).

Further compounding the likelihood of confusion by the jury is the fact that Merck's own experts, Dr. Betts and Dr. Gruber, have no independent opinion concerning whether Dr. Alexander violated the standard of care in his treatment of Mrs. Secrest. (Betts depo., pp. 70-73; Gruber depo., p. 41). Thus if record evidence is admitted concerning the disciplinary proceedings involving Dr. Alexander, Merck's own experts are not in a position to comment

upon those conclusions and the disciplinary proceedings records are not subject to cross-examination. This would mean that there would be no witness offered by Merck to explain the significance, if any, of these documents. The confusion in the jury's minds that would occur as a result is self-evident.

Furthermore, admission of the factual allegations and legal conclusions included in the administrative complaint and stipulation would serve to undermine the exclusive province of the jury in this case. *See United States v. McDonald,* 688 F.2d 224, 230 (4th Cir. 1982) (holding trial court properly excluded Army investigator's findings and conclusions because probable cause report "tend[ed] to undermine the exclusive province of the jury.")

In sum, exclusion of the administrative complaint and stipulation and any testimony concerning these documents is warranted under FRE 403. Such evidence and/or testimony would constitute a cumulative presentation of evidence. As the information underlying these allegations and conclusions is equally available to Merck's expert witnesses, there is no independent probative value to the documents themselves. Moreover, there is a great risk that the jury would attach undue weight to the factual allegations and legal conclusions included within the administrative complaint, thus severely prejudicing Mrs. Secrest.

II. MERCK SHOULD BE PROHIBITED FROM ARGUING THAT DOCTORS VOTE ON THE EFFICACY AND SAFETY OF FOSAMAX WITH THEIR PRESCRIPTION PADS.

In the prior bellwether trial case of *Graves v. Merck*, Merck argued that the benefits outweigh the risks and evidence of that is found in what millions of doctors do: "The FDA has confirmed that over and over again, practicing physicians have confirmed that over and over again. They vote with their prescription pads." (Graves TR, p. 2053, Exh. 12); "Well established

efficacy; benefit exceeds risk, physicians voting with their prescription pads, 190 million prescriptions." (Graves TR, p. 2056.) Merck should not be permitted to argue that doctors vote on the efficacy and safety of Fosamax when they write prescriptions for Fosamax unless Plaintiff is permitted to introduce evidence of the massive marketing onslaught Merck has engaged in to induce those physicians to prescribe Fosamax to millions of women.

The prescribing practices of physicians around the world is not relevant to the issues in this case. The jury in this case will be tasked with deciding whether the benefits of Fosamax outweighs its risks for Mrs. Secrest. The prescribing practices of physicians who have not treated Mrs. Secrest and will not testify in this case is simply not relevant to the disposition of this case. The choice to prescribe Fosamax, or any drug, to a patient is a very fact specific decision that cannot simply be boiled down to a catch phrase. Furthermore, even if the Court finds some probative value to Merck's argument concerning every doctor's prescribing practices, this limited probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury. See FRE 403.

Permitting Merck to argue that doctors vote on the safety and efficacy of Fosamax "with their prescription pads" will create a serious danger of unfair prejudice to Mrs. Secrest. Mrs. Secrest would be left to argue a point concerning a group of physicians that have never treated or even seen Mrs. Secrest. Mrs. Secrest has no way to cross-examine this vast group of unnamed physicians to determine if they actually believe that Fosamax's benefits outweigh its risks or under what circumstances they hold such a belief.

Permitting such an argument would also serve to confuse the issues and mislead the jury in this case. The issue in this case is not whether the benefits of Fosamax outweigh its risks for

all patients, but whether the benefits of Fosamax outweighed the risks for Mrs. Secrest, while she was taking the drug. Therefore, the jury could be left believing that they were responsible for rendering a verdict on the efficacy and safety of Fosamax for all patient populations, when in fact, their task is much more limited. As such, the Court should limit the testimony in this case to the safety and efficacy of Fosamax for patients like Mrs. Secrest, rather than allow Merck to speak for every physician in the world prescribing, for any and every, patient population.

If the Court permits Merck to argue that doctors vote on the safety and efficacy of Fosamax "with their prescription pads", then the Court should also rule that the door has been opened to Merck's entire marketing scheme for Fosamax. After all, if Merck is permitted to opine on every physician's opinion of Fosamax, then Mrs. Secrest should also be permitted to show the jury the marketing scheme Merck employed to sway the opinions of these same physicians. Anything less would prohibit a full presentation of the evidence relevant to physicians prescribing practices for Fosamax.

III. THIS COURT SHOULD PRECLUDE ANY REFERENCE TO THE WEBSITE WWW.HUGESETTLEMENTS.COM.

During the *Graves* bellwether trial, defense counsel asked Plaintiff's regulatory expert, Dr. Suzanne Parisian, whether her name had appeared on a website known as "hugesettlements.com". (Graves TR, p. 770.) Dr. Parisian responded that it had but that she had nothing to do with it and wrote a letter about it. (Graves TR, p. 770.) She was cut off and defense counsel focused the question whether her name had appeared on hugesettlements.com. (Graves TR, p. 770.) On redirect, Dr. Parisian testified as follows:

> Q: Dr. Parisian, Mr. Brock asked you several questions, but first he asked you about something, I wrote it down, it was called a website, I think it was

Huge Settlements.com?

A: Yes, sir.

Q: And you started to answer about that, and I know I want to hear all about it. So what's the story with Huge Settlements.com, what is that all about?

A: It came up in another proceeding about three years ago, and I went to the website. The website is attorneys website, and somehow you had to go through a maze to ever find that I was even on the website. So I called up the website and I wrote a letter to ask that they remove my name because I had never put my name on the website. I asked what the source of my name on that website was, and the web master didn't know. But I, when I became aware of it, I removed it. I have a letter to document that.

Q: Do you know if it was removed?

A: I couldn't find it to begin with.

(Graves TR, p. 810.)

As Dr. Parisian began to explain to defense counsel, she had nothing to do with placing her name on the website. She wrote a letter to the website and demanded that her name be removed from the website as Dr. Parisian had no information about how her name appeared on the website. (02/25/08 ltr. from Dr. Suzanne Parisian to HugeSettlements.com, Exh. 10 hereto.)

This Court should exclude this evidence as hearsay evidence without exception as the declarant is unknown and the circumstances of how her name appeared on the website has never been established - - other than Dr. Parisian's testimony that she had nothing to do with her name getting placed there. Therefore, it constitutes inadmissible hearsay under Federal Rule of Evidence 801 and 802. "Where posting from internet sites are not statements made by declarants testifying at trial and are offered to prove the truth of the matter asserted, such postings generally constitute hearsay under FRE 801." *Nowack v. Tucows, Inc.*, 73 Fed. R. Evid. Serv. 331, 2007

WL 922306, *5 (E.D.N.Y. 2007) (citing *United States v. Jackson*, 208 F.3d 633, 638 (7th Cir. 2000); *see also Loussier v. Universal Music Group, Inc.*, 2005 WL 5644421, *4 (S.D.N.Y. 2005) (Wood, J.) (ruling that e-bay print-outs which lacked authentication were inadmissible hearsay under Rules 801 and 802). Further, the probative value of this is non-existent and the danger of unfair prejudice outweighs any probative value and this Court should exclude reference to the website and someone placing Dr. Parisian's name on that website pursuant to FRE 403.

IV. THIS COURT SHOULD EXCLUDE ANY EVIDENCE OR QUESTIONS RELATING TO THE HEALTH OR DEATH OF FRANK SECREST.

As this Court is aware, this Court adjourned the trial of the Secrest case because Frank Secrest Trecently had been hospitalized for pulmonary complications resulting from a bacterial and fungal infection, and congestive heart failure. Sadly, Mr. Secrest died from lung cancer shortly after the adjournment was announced. This Court has now dismissed the consortium claim of Frank Secrest. Thus, Mr. Secrest's medical condition and death are not at issue in Mrs. Secrest's product liability case against Merck.

This Court should exclude any questions or evidence concerning his medical condition or death as it is irrelevant under FRE 401 and 402 and under FRE 403 any probative value is far outweighed by the risk of undue prejudice.

V. THIS COURT SHOULD PRELUDE ARGUMENT RELATING TO EVIDENCE THAT HAS BEEN EXCLUDED OR LIMITED BY THE COURT.

During the *Graves* trial, this Court excluded Dr. Marx's opinions relating to what caused his patients osteonecrosis of the jaw. Over objection by Plaintiff's counsel, Merck's attorneys expressly argued about Dr. Marx not offering any opinion about causation and inferring that that must mean that he believes something other than Fosamax caused osteonecrosis of the jaw:

> Now, there has been an issue in the case about length of use. So even amongst folks who think there may be a relationship between bisphosphonates and ONJ, they believe that duration of use is a significant issue. This is Dr. Marx, who came and testified. And he's saying in 2007 it takes six monthly doses of intravenous bisphosphonates to place a patient at risk for BIONJ, which is contrasted to three years or 156 continuous weekly doses that are required to place patients who take Fosamax or Actonel into the risk range for this disease state.
>
> Please note, Dr. Marx treated this patient extensively. He did not tell you Fosamax causes injury.
>
> MR. O'BRIEN: Your Honor, I move to strike that. That is inappropriate in light of the prior application.
>
> THE COURT: Overruled.
>
> MR. BROCK: Dr. Marx came to this court. He testified extensively about all the surgeries that he conducted, and not one word did he say that Fosamax caused or contributed to this injury.

(Graves trial TR, p. 2079.)

It is well settled that it is improper argument to comment on evidence that has been excluded or limited by the trial court and it is particularly inappropriate for counsel to comment upon the absence of evidence when there was evidence but the evidence was excluded at the request of the commenting counsel. *See United States v. Duncan*, 308 Fed. Appx. 601, 606 (3rd Cir. 2009) (finding prosecutor's comments regarding lack of evidence produced by defendant on issue of witnesses' motives to lie improper, when such evidence had previously been excluded at the prosecutor's urging); *Carnival Corp. v. Pajares*, 972 So.3d 973, 975-76 (Fla. 3rd DCA 2008) (holding defense counsel's comment about lack of testimony by plaintiff's witness regarding standard of care was improper in light of the fact that the testimony was excluded in limine after successful efforts by defense counsel). Courts have concluded that such tactics amount to the "ultimate gotchasim by whipsawing the plaintiff" for not producing the very evidence that

defense counsel has successfully excluded. *Hernandez v. Home Depot, Inc.*, 695 So.3d 484, 485 (Fla. 3rd DCA 1997).

Accordingly, to the extent this Court has excluded testimony of witnesses on either the *Daubert* motion or the motions in limine, this Court under FRE 403 should exclude argument about the absence of that excluded evidence as it is likely to mislead the jury into thinking that a witness did not offer the testimony because it was not helpful to the offering party's case.

VI. THIS COURT SHOULD ADOPT THE FOLLOWING RULINGS AND INCORPORATE THEM INTO THE *SECREST* CASE.

A. This Court Should Preclude Merck from Offering Testimony or Argument Inconsistent with the Supreme Court's Recent Holding in *Wyeth v. Levine.*

This Court previously granted this motion as Plaintiff's No. 1 at the Shirley Boles v. Merck & Co. motion in limine hearing of July 29, 2009, at page 473 of the hearing transcript (Exh. 5 hereto).

Plaintiff anticipates that Merck will offer testimony and argument at trial that it could not have changed the Fosamax label to include language pertaining to oral adverse events without prior approval of the FDA. Such claims are not only false but will mislead and prejudice the jury by suggesting that the company is not responsible for its own warning or any delays in amending the label information. Moreover, such testimony would convert this case into a trial about the FDA's conduct rather than Merck's failure to provide adequate warnings in its label.

Any suggestion that Merck could not have changed the Fosamax label without prior FDA approval is false and misleading. Though subject to FDA oversight, Merck was responsible for ensuring that adequate warnings appeared in the Fosamax label at all times. The Food, Drug and Cosmetic Act (the "Act") expressly requires a drug manufacturer to immediately inform the

public of newly discovered dangers rather than waiting for the FDA to act. *Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs,* 44 Fed. Reg. 37434, 37447 (1979). It is the legal obligation of a drug manufacturer to promptly take steps to strengthen its warnings to physicians and consumers of newly discovered dangers and risks of an approved product. *Wyeth v. Levine*, 129 S.Ct. 1187, 1198-99 (March 4, 2009). Any argument to the contrary should be excluded.

The intention of the Act is "to protect consumers from dangerous products." *United States v. Sullivan,* 332 U.S. 689, 696 (1948). Consistent with its purpose, the FDA and its regulations explicitly permit a manufacturer to unilaterally strengthen a warning label at any time without regulatory approval, 21 C.F.R. § 314.70(c)(6)(iii)(A), to allow the drug manufacturer to quickly strengthen warnings when evidence of side effects, risks, or dangers are discovered. *See* 30 Fed. Reg. 993 (Jan. 30, 1965); 21 C.F.R. § 201.57 ("labeling shall be revised to include a warning *as soon as there is reasonable evidence of an association of a serious hazard wit ha drug; a causal relationship need not have been proved*") (emphasis added); 21 C.F.R. 314.70(c)(6)(iii) (labeling changes to "add or strengthen a contraindication, warning, precaution, or adverse reaction" do not require FDA's prior approval).

In *Wyeth v. Levine*, the United States Supreme Court rejected the notion that the FDA regulatory scheme preempts state tort law suits. 129 S.Ct. at 1191. In so ruling, the Court painstakingly detailed the regulatory history of the FDA and, more importantly, the limitations of the regulatory scheme. *Id.* at 1195-97.

Prior to 2007, the FDA lacked statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval. *Id.*

at 1196, 1198. While the 2007 statutory authority change gave the FDA broader powers than it had before, the accompanying rule of construction made clear that drug manufacturers remain responsible for updating their label and FDA pre-approval still is not necessary before any such change is made. *Id.* Accordingly, both before and after 2007, the FDA's "changes being effected" regulations provides that manufacturers may add or strengthen safety language without prior approval from the FDA. *Id.* (citing 21 C.F.R. " 314.70(c)(6)(iii)(A), (C)).

In *Levine*, Wyeth argued that had it unilaterally added a warning or precaution to its Phenergan label, it would have violated federal law governing unauthorized distribution and misbranding. *Id.* at 1197. The Supreme Court unequivocally rejected that argument as fallacious:

> Wyeth's cramped reading of the CBE regulation and its broad reading of the FDCA's misbranding and unauthorized distribution provisions are premised on a more fundamental misunderstanding. Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. *See, e.g.*, 21 C.F.R. § 201.80(e) (requiring a manufacturer to revise its label to include a warning as soon as there is a reasonable evidence of an association of a serious hazard with a drug); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 (Manufacturers continue to have a responsibility under Federal law . . . . to maintain their labeling and update the labeling with new safety information).

Id. at 1198-99.

The *Levine* Court expressly rejected the notion that the FDCA provides a floor and a ceiling for drug regulation, and ruled that the infamous 2006 regulatory preamble was entitled to no deference as it did not proceed through appropriate regulatory channels and is contrary to the agency's long-standing views related to its powers. *Id.* at 1199-1201.

As the Court observed: "The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the new postmarketing phase as new risks emerge." *Id.* at 1202. In so observing, the Court relied upon an extensive field of assessments of the powers of the, which include the following conclusions:

- [T]he Agency suffers from serious scientific deficiencies and it not positioned to meet current or emerging regulatory responsibilities. FDA Science Board, Report of the Subcommittee on Science and Technology: FDA Science and Mission at Risk 2, 6 (2007);

- The [FDA] lacks the resources needed to accomplish its large and complex mission . . . . There is widespread agreement that resources for postmarketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand this essential component of its mission. National Academies, Institute of Medicine, the Future of Drug Safety: Promoting and Protecting the Health of the Public 193-194 (2007);

- FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarketing safety issues.GAO, Drug Safety: Improvement Needed in FDA's Post-market Decision-making and Oversight Process 5.

Id. at 1202, n.11.

The Court should therefore enter adopt its order precluding Merck from arguing or offering testimony that it could not amend the Fosamax label to include warnings or precautions concerning risks without prior FDA approval. Such testimony or argument would be false, contrary to well-settled law, and would only serve to mislead to the jury.

B. Merck Should Not Be Permitted to Introduce Testimony That Any Merck Employee or Any Employee's Family Member Takes or Has Taken Fosamax.

This Court previously granted this motion as Plaintiff's No. 4 at the Shirley Boles v. Merck & Co. motion in limine hearing of July 29, 2009, at pages 474-76 of the hearing

transcript (Exh. 5 hereto).

Defendant's witnesses should be precluded from discussing whether they or their family members took Fosamax because such testimony is irrelevant to the issues of this case. Under FRE 402, only relevant evidence is admissible. Furthermore, FRE 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Further, there has never been a disclosure in any of the discovery presented by Merck to date that any Merck expert or Merck employee will testify that he or she took Fosamax. Therefore, this Court should exclude any such evidence under Federal Rule of Civil Procedure 37 as well.

C. Evidence of Merck's "Good Character" Is Irrelevant to the Claims at Issue.

This Court previously granted this motion as Plaintiff's No. 5 at the Shirley Boles v. Merck & Co. motion in limine hearing of July 29, 2009, at page 476 of the hearing transcript (Exh. 5 hereto).

Any evidence or discussion that Merck is a "good company" and performs benevolent acts has no relevance to the claims asserted by Plaintiff and must be excluded under the Federal Rules of Evidence. FED. R. EVID. 401 and 404. "'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED R. EVID. 401. Furthermore, "[e]vidence of a person's character or a trait of character is not admissible for the purpose of proving action in conformity therewith on a particular occasion[.]" FED. R. EVID. 404.

In the instant case, whether Merck is a "good company", gives away prescriptions drugs

in foreign countries, or makes drugs that cure disease has absolutely no bearing on Merck's knowledge of the dangers of Fosamax, the adequacy of Merck's label and in particular, the injuries suffered by Mrs. Graves. Merck's character is not an element of any claim or defense. Such evidence is neither legally nor logically relevant to any fact that is of consequence in this matter, and must be excluded. *See, e.g., Niver v. Travelers Indem. Co. of Illinois*, 433 F.Supp.2d 968, 994 (N.D. Iowa 2006) (excluding, pursuant to Rules 401, 402, and 404, evidence of good and charitable acts by Travelers).

D. This Court Should Preclude or Limit the Introduction of Evidence Pertaining to Non-Osteonecrosis of the Jaw Risks Associated with Plaintiff's Other Prescription Medications.

This Court previously granted this motion as Plaintiff's No. 9 at the Shirley Boles v. Merck & Co. motion in limine hearing of July 29, 2009, at page 477-78 of the hearing transcript (Exh. 5 hereto), as to cigarette smoking. Additionally, and for the same reasons which served as the basis for the Court's ruling in Boles, this Court also preclude evidence of non-osteonecrosis of the jaw risks of other non-bisphosphonate medications taken by Judith Graves, at pages 5-6 of the October 20, 2010, motion in limine transcript (Exh. 11 hereto).

This Court should exclude evidence regarding non-osteonecrosis of the jaw risks of drugs other than Fosamax. For instance, during the deposition of Linda Secrest, defense counsel asked several questions relating to the non-osteonecrosis of the jaw risks of other medications Mrs. Secrest was taking, including Aranesp, Aygestin, Bextra, and hormone replacement therapy. (Secrest depo., pp. 89-95.) This Court's ruling prior ruling shows that this is simply risk propensity evidence that should be excluded: "Merck may not introduce evidence that plaintiff disregarded the risks of smoking to show that Ms. Boles would likely have disregarded the risk

of ONJ. Essentially, Merck would like to argue, 'Once a risk taker, always a risk taker.' This would be using evidence of a character trait to show propensity, a purpose that I understand Rule 404 of the Federal Rules of Evidence to forbid." (Exh. 5, pp. 477-78.)

The same analysis applies here: i.e., that either she or her physician were willing to accept the risks of a non-osteonecrosis of the jaw condition for a medication other than Fosamax. This trial is about Fosamax and what it did to Linda Secrest. It should not devolve into a set of mini-trials regarding the risks of other prescription medications which are irrelevant to the issue of whether Fosamax caused Mrs. Secrest's jaw problems.

E. This Court Should Preclude Merck from Appealing to the Jurors' Self-interest Through Fear-Mongering and Arguing or Inferring That a Verdict Takes a Prescription Choice Away from Doctors.

This Court previously granted this motion during the Graves v. Merck & Co. motion in limine hearing of October 20, 2010, at page10-11 of the hearing transcript and instructed defense counsel to present to the Court any questions which might impact or appeal to jurors' self-interest. (Exh. 11 hereto).

This Court should preclude Merck from improperly "stepping into the jury box" and introducing evidence or argument that infers to the jury that it will be impacted by the decision in Mrs. Secrest's case. During the *Boles* 2010 trial, Merck's expert Dr. John Bilezikian stood directly in front of the jury and engaged in fear-mongering. Dr. Bilezikian testified about hip fractures as follows:

> Another big number is 300,000 hip fractures, which is the biggest and most dangerous complication of this disease.
>
> Now, the hip fracture is not just a broken bone. In the first year, after a hip fracture, in this country, there is a mortality rate, that is people die from this disease. That fracture leads to death in

> somewhere between 25 and 30 percent of the population. So the mortality, death, is up to 30 percent in the first year.
>
> Now, those who don't die have troubles. About 30 to 40 percent of them have dependency needs. They're not able to return to their formal [sic] lifestyle. They may have to use a cane. They may have to have someone at home to help them. And there are as many as eight percent of these individuals who actually never go home. They aren't able to.
>
> * * * * *
>
> They never go home. They go to a long-term care facility because they are not able to go home.

(Boles 2010 trial TR, , p. 1452, Exh. 6 hereto.) Of note, Dr. Bilezikian concluded, as he pointed directly at the jury, that "it's a dangerous disease for what it can do potentially to everyone of us because everyone of us in this courtroom, if we live long enough and if we don't do something about this disease, will be a statistic like this." (Boles 2010 trial TR, p. 1452.)

Defense counsel repeatedly argued that the *Boles* 2010 trial directly concerned "choices" available to physicians. For instance, at the very inception of the case, in opening statements, defense counsel told the jury:

> Not all drugs work for everyone, but doctors need a choice. Doctors need a choice. Do they want to use a drug to build bone density, that builds bone for their patients? Doctors need that choice, and the FDA made sure that doctors got that choice for women with low bone density.
>
> And I think we need to look at what the FDA's decision meant for American women for their choice for preserving their bone and building bone density. What the FDA has decided, if we think about all women, I just put up nine photographs there, women with their doctors. If we think about all women, women with negative 2.5 on that bone density score, fracture reduction risk, overwhelming evidence, even the lawyers for the plaintiff can see that this, as you heard him say, this is a good drug, not defective. So for those women, for many women, there's a concession here. I

> heard it clearly. This is a good drug and not defective for many women. But what they argue is that this good drug that helps many women is at the same time as it's good, it's also defective. What they argue is that for some women, women with a little bit better bone density, that those women, even though it's FDA approved for those women to help them prevent getting bone loss, even though it's FDA approved for them, even though there's overwhelming evidence it will prevent bone loss for them, just like it did for Mrs. Boles, what the lawyers for the plaintiff argue is that doctors should not be able to choose Fosamax for those women.
>
> That's what their argument is. It's defective for those women, so doctors for those women should not be able to choose. That's exactly what they're asking in this case. Those women and their doctors should not have the choice. The FDA has decided those women and their doctors should have that choice, and that is our position in this case, the same as the FDA's.

(Exh. 6: 130-32.)

Coupled with Dr. Bilezikian's testimony that unless jurors do something about osteoporosis (i.e., take Fosamax), they will end up a statistic, defense counsel's arguments that the case is about whether physicians should have a "choice" is improper and misleading, under Federal Rule of Evidence 403. Nothing in Mrs. Secrest's case will impact whether Fosamax is available as a choice to physicians. This is not a case that will result in Merck being required to pull Fosamax from the shelves. Defense counsel and the defense witnesses should be precluded from appealing to the jurors' self-interest through fear-mongering and argument that the verdict will impact the ability of physicians to choose Fosamax as a medication for their patients as that appeals to the jurors' self interest as well as to issues beyond the case at hand *See, e.g., Allstate Ins. Co. v. James*, 845 F.2d 315, 318-19 (11th Cir. 1988) (holding that trial judge committed reversible error by failing to sustain objection to closing remarks of insurer's counsel that suggested jury had power to control cost of insurance through verdict for insurer); *and United*

States v. Waters, - - - F.3d - - - 2010 WL 3565259, *11 (9th Cir. 09/15/10) (holding that prosecutor's appeal to juror self-interests constituted reversible error).

F. This Court Should Preclude in Limine Counsel from Inferring or Arguing That the Court Has Any Particular View of the Evidence of the Case.

This Court previously granted this motion in the Judith Graves v. Merck & Co. motion in limine hearing of October 20, 2010, at pages 12-13 of the hearing transcript (Exh. 11 hereto).

All counsel should be precluded from referring to this Court taking issue with a witnesses' testimony for, as the Court has instructed counsel and the juries, the Court has no view of the evidence and no counsel should infer that the Court has a view of any particular piece of evidence. For instance, during the closing arguments in the *Boles* 2010 trial, defense counsel chided Plaintiff's expert, Dr. Curt Furberg's, about several aspects of his testimony. Counsel specifically referred to the Court's analogy of the Court's wife writing a check which the Court then signs when it gets home to the issue of Merck writing the Fosamax label and the FDA approving the label. (Exh. 6: 1625-26.) As this Court is all too aware, at the same time, defense counsel had on powerpoint a check payable to "The Truth" signed by "John F. Keenan", as if this Court had any particular view of the evidence in the case that should be cited to the jury. This Court should preclude all counsel from referring to comments from the Court as it unfairly infers that the Court views the evidence in any particular way and is thus misleading and excludable under Federal Rule of Evidence 403.

CONCLUSION

For the foregoing reasons, Plaintiff Linda Secrest respectfully requests this Court grant Plaintiff's Motion in Limine and enter an Order excluding in limine the lines of evidence and argument discussed above.

* * *

RESPECTFULLY SUBMITTED, this 2d day of August, 2011.

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CERTIFICATE OF SERVICE

On this 2nd day of August, 2011, I certify that I filed by ECF and sent by first class U.S. Mail a copy of the foregoing to the following:

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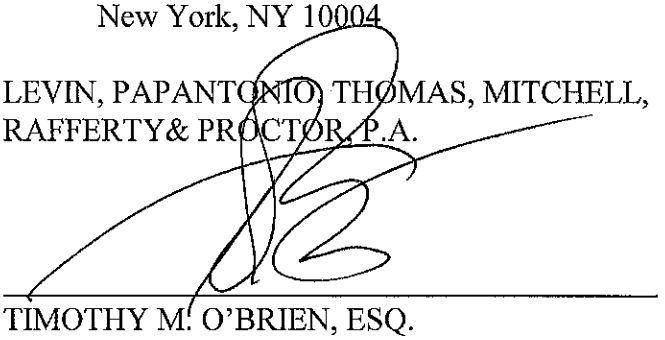

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